

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE

CHUGAI PHARMACEUTICAL CO., LTD.,	)	
	)	
Plaintiff,	)	
	)	
v.	)	C.A. No. 18-1802 (MN)
	)	
ALEXION PHARMACEUTICALS, INC.,	)	
	)	
Defendant.	)	

**ORDER**

At Wilmington, this 4th day of October 2021;

In April 2020, the Court held a hearing to address the construction of four disputed terms in U.S. Patent Nos. 9,890,377 (“the ’377 Patent”) and 10,472,623 (“the ’623 Patent”), which share a common specification. During summary judgment proceedings, it became apparent that there was a latent dispute about the scope of the term “an individual in need of having an antigen removed from the individual’s plasma,” which appears in some form<sup>1</sup> in the method claims of the two patents. The Court accepted additional submissions on this issue. (D.I. 358 & 359).

Plaintiff asserts that the term means “an individual that benefits from having an antigen removed from the individual’s plasma by binding of the antibody to the antigen in the plasma and preventing it from being biologically active, or transporting the antigen to the endosome for release and/or degradation of the antigen.” (D.I. 359 at 1). Defendant does not offer a complete construction but asserts that “the term ‘removed’ requires the physical displacement of the antigen from the plasma and the inclusion of ‘individual in need of’ in a method claim requires performing the method with the intent or for the purpose of achieving the removal of the antigen.” (D.I. 358

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<sup>1</sup> The claims reference either “identifying” or “administering an antibody to” such an individual in need.

at 1). Thus, according to Defendant, “the Court [should] construe these terms to require performance of the step ‘with the intent or for the purpose of physically displacing an antigen from the individual’s plasma.’” (*Id.*).

The dispute between the parties is thus two-fold: (1) whether the phrase “an individual in need” invokes an intent requirement (as Defendant proposes) and (2) whether removal as recited in the claims requires physical displacement of the antigen from the plasma or also includes preventing the antigen from being biologically active. The Court addresses each in turn.

### **1. “Individual in Need”**

Defendant argues that *Jansen v. Rexall Sundown, Inc.*, 342 F.3d 1329 (Fed. Cir. 2003), requires that “an individual in need” means the claimed method must be performed with the intent or for the purpose of achieving the removal of the antigen. The Court disagrees.

In *Jansen*, the claim was directed to a method of “treating or preventing macrocytic-megaloblastic anemia . . . which comprises administering a . . . dosage of a vitamin preparation to a human in need thereof.” *Id.* at 1330. The method claims thus required both treating (or preventing) a stated condition and doing so in a human in need thereof, and the *Jansen* court emphasized this dual requirement in reaching its conclusion that an “intent” was required. *See id.* at 1333 (“We need not decide whether we would reach the same conclusion if either of the ‘treating or preventing’ phrase or the ‘to a human in need thereof’ phrase was not a part of the claim; together, however, they compel the claim construction arrived at by both the district court and this court.”). Similarly, the other cases cited by Defendant to support imposition of an “intent” limitation also involved claims reciting both elements: a condition to be treated and an individual in need thereof. *See Rapoport v. Dement*, 254 F.3d 1053, 1056 (Fed. Cir. 2001) (“A method for treatment of sleep apneas . . . to a patient in need of such treatment.”); *Sanofi v. Glenmark Pharm.*

*Inc.*, No. 14-264-RGA, 2015 WL 5092631 \*2, 6 (D. Del. Aug. 28, 2015) (“A method of decreasing a risk of hospitalization for atrial fibrillation in a patient having a history of atrial fibrillation or atrial flutter . . . to a patient in need thereof”). Here, however, the claims do not recite a specific condition to be treated through removing the antigen from an individual’s plasma. Thus, the Court finds *Jansen* inapplicable and rejects Defendant’s attempt to read an intent element into the claims.

That leaves Plaintiff’s proposed construction that “in need of” means “benefits from.” The Court finds this construction unnecessary. As Judge Bryon has recognized, the phrase “a person in need thereof” appears frequently in patents on pharmaceutical products and methods of treatment.” *Erfindergemeinschaft Uropep GbR v. Eli Lilly & Co.*, No. 2:15-CV-1202-WCB, 2016 WL 7042234, at \*4 (E.D. Tex. Aug. 11, 2016). The words are neither complex nor difficult to understand. Indeed, they seem to be sufficiently clear, not only to persons of skill in the art, but also to laypersons on a jury. Thus, the term “person in need thereof” needs no construction.

## **2. “Removed”**

The dispute about the word “removed” is whether the antigen must be physically displaced from the plasma, as Defendant asserts, or whether “removed” also includes deactivating the antigen in the plasma, as Plaintiff argues. The intrinsic evidence supports Plaintiff’s proposal.

During prosecution of the ’623 Patent, Plaintiff pointed to portions of the specification that described “a mechanism by which this genus of antibodies provides for the more effective removal of antigen from plasma.” (D.I. 339, Ex. E at p. 21 (March 20, 2019 Amendment) (citing paragraph [0234] of the patent application, which corresponds to column 27, lines 28-50 of the ’623 patent)). The cited section of the specification describes: binding of the antibodies to the antigen in the plasma to “neutralize” biological activity; the “translocat[ion]” of the antigen-antibody complex into the cell where the antigen is degraded; and the recycling of the antibody to the plasma to bind

and “neutralize” additional antigens. That the applicant pointed to these sections as addressing removal supports the conclusion that removal of antigen from plasma includes binding and neutralization of the antigen by the antibody (without physical displacement). (*See also* ’623 Patent at 19:39-41 (“Thus, ‘bind’ can be replaced with ‘neutralize’ when the antibody is a neutralizing antibody”); *id.* at 29:16-20 (“Accordingly, when the antigen-binding molecule is, for example, an antigen-binding neutralizing molecule, the antigen-binding molecule that easily dissociates from the antigen under the endosomal acidic condition can bind and neutralize antigens multiple times.”)).<sup>2</sup>

The working examples of the ’623 Patent also support that removal of antigen from plasma includes neutralization of the antigen. For example, Example 2 describes a “Method for Creating Antibody Capable of Neutralizing Antigen Multiple Times.” (’623 Patent at 56:60-61). Example 18 pertains to “Repetitive Binding to Antigen by pH-Dependently Binding Antibody.” (*Id.* at 85:33-35). These examples disclose that pH-dependent IL-6R antibodies bind to more antigens (IL-6R) in plasma and more effectively neutralize antigens compared to antibodies that are not pH-dependent.<sup>3</sup>

Additionally, in applications related to the patents asserted here, the Patent Office has recently referenced the claims of the ’623 Patent and noted that those claims are directed to “a method for removing an antigen from plasma (neutralizing an antigen *in vivo*).” Although this is not intrinsic evidence and appears to be of limited relevance, it is not wholly without probative value. And to the extent it is probative, it supports Plaintiff’s proposed construction. Thus, the

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<sup>2</sup> There is no dispute that specifications also describe antigen removal by physical displacement from the plasma as antigen elimination.

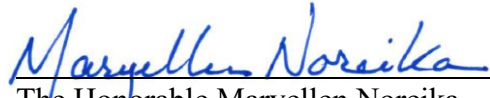
<sup>3</sup> The examples also disclose that IL-6R antibodies remove antigens (soluble IL-6R) by transporting the antigens to the endosome and releasing them for degradation.

Court concludes that “removed” encompasses physical displacement of the antigen from the plasma, as well as preventing the antigen from being biologically active.

THEREFORE, IT IS HEREBY ORDERED that:

1. The claim term “an individual in need of having an antigen removed from the individual’s plasma” means “an individual in need of having an antigen removed from the individual’s plasma by binding of the antibody to the antigen in the plasma and either preventing it from being biologically active, or physically displacing it from the plasma.”

2. As there appear to be genuine issues of material fact as to whether the accused method involves administration or identifying of “an individual in need,” Plaintiff’s motion for summary judgment of infringement (D.I. 278) is DENIED.

  
The Honorable Maryellen Noreika  
United States District Judge